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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,690	05/21/2007	Rosanne D. Dunn	29729/38914	2874

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EXAMINER	
SCHWADRON, RONALD B	
ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,690	DUNN ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 28,29,31-38, 43,44,47,48 are rejected under 35 U.S.C. 102(b) as being anticipated by Uhr et al. (US Patent 4,792,447). Applicants arguments have been considered and deemed not persuasive.

Uhr et al. teach antibody against lambda light chain wherein said antibody binds lambda light chain on tumor cells and wherein said antibody is conjugated to a toxin (see column 4, first paragraph and column 3, first paragraph and last paragraph). The antibody would bind the forms of lambda light chain found on the surface of tumors. The antibody is labeled with a detectable moiety (aka a toxin). The conjugate is prepared in a diluent (for example see column 8, first complete paragraph). The conjugate is used to treat B cell tumors including B cell leukemia/lymphoma (see column 3, first paragraph and column 1, third paragraph). Uhr et al. disclose the method of claim 38 wherein the autologous bone marrow contains hematopoietic progenitor cells (see column 14, first paragraph). The method of Uhr et al. uses a chemotherapeutic agent (see column 15, second paragraph), wherein chemotherapeutic agents have the functional effect recited in claim 36 (see claim 37).

Regarding applicants comments, Example 1 in the specification discloses antibodies that bind free lambda light and also bind lambda light chain in association with Ig heavy chain (aka Mab 1306 and mab ME 154). Furthermore, the specification, page 41, Example 2 discloses:

Flow cytometry results indicate that L7, mabl306 and ME 154 all **bind specifically** to a cell surface antigen on LP-1 myeloma cells (Figure 3).

The "cell surface antigen" referred to is LMA. Thus, said passage indicates that "specifically binds" as used in the specification would encompass anti lambda antibodies which bind free lambda chain or lambda chain associated with heavy chain. Regarding applicants comments about the specification, page 14, all of the aforementioned antibodies bind lambda light chain and do not bind other proteins.

Applicants arguments involve limitations currently not recited in the claims under consideration.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 30, 28,29,31-38, 43,44,47,48 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Uhr et al. (US Patent 4,792,447) in view of Bergsagel et al. Applicants arguments have been considered and deemed not persuasive.

Uhr et al. teach antibody against lambda light chain wherein said antibody binds lambda light chain on tumor cells and wherein said antibody is conjugated to a toxin(see column 4, first paragraph and column 3, first paragraph and last paragraph). The antibody is labeled with a detectable moiety (aka a toxin). The conjugate is prepared in a diluent (for example see column 8, first complete paragraph). The conjugate is used to treat B cell tumors including B cell leukemia/lymphoma (see column 3, first paragraph and column 1, third paragraph). Uhr et al. disclose the method of claim 38 wherein the autologous bone marrow contains hematopoietic progenitor cells (see column 14, first paragraph). The method of Uhr et al. uses a chemotherapeutic agent (see column 15,

second paragraph), wherein chemotherapeutic agents have the functional effect recited in claim 36 (see claim 37). Uhr et al. do not teach that said method can be used to treat multiple myeloma. Bergsagel et al. teach that multiple myeloma cells can express lambda light chain on the cell surface (see abstract). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Uhr et al. teach antibody conjugate against lambda light chain wherein said antibody binds lambda light chain on tumor cells and wherein the conjugate is used to treat B cell tumors whilst Bergsagel et al. teach that multiple myeloma cells can express lambda light chain on the cell surface. One of ordinary skill in the art at the time the invention was made would have been motivated to he aforementioned because Uhr et al. teach antibody conjugate against lambda light chain wherein said antibody binds lambda light chain on tumor cells and wherein the conjugate is used to treat B cell tumors whilst Bergsagel et al. teach that multiple myeloma cells can express lambda light chain on the cell surface.

Applicants arguments are as per addressed above.

5. Claims 28,29,31-48 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Uhr et al. (US Patent 4,792,447) in view of Ruben et al. (US 2005/0255532). Applicants arguments have been considered and deemed not persuasive.

Uhr et al. teach antibody against lambda light chain wherein said antibody binds lambda light chain on tumor cells and wherein said antibody is conjugated to a toxin(see column 4, first paragraph and column 3, first paragraph and last paragraph). The antibody is labeled with a detectable moiety (aka a toxin). The conjugate is prepared in a diluent (for example see column 8, first complete paragraph). The conjugate is used to treat B cell tumors including B cell leukemia/lymphoma (see column 3, first paragraph and column 1, third paragraph). Uhr et al. disclose the method of claim 38 wherein the autologous bone marrow contains hematopoietic progenitor cells (see column 14, first paragraph). The method of Uhr et al. uses a chemotherapeutic agent (see column 15, second paragraph), wherein chemotherapeutic agents have the functional effect recited in claim 36 (see claim 37). Uhr et al. do not teach the method of claims 39-42 or antibodies of claims 45,46. Ruben et al. teach therapeutic use of chimeric antibodies (see [0029] and [0218]). Ruben et al. teach in vivo diagnostic use of an antitumor

antibody labeled with a radioisotope (see [0261] and [0362]). Ruben et al. teach that the antibody can be conjugated to heterologous polypeptides or nucleic acids encoding such molecules such as cytokines (see [0261],[0294],[0373],[0375],[0440],[0366]). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Uhr et al. teach antibody against lambda light chain wherein said antibody binds lambda light chain on tumor cells and conjugates thereof wherein said conjugates are used to treat B cell tumors whilst Ruben et al. teach therapeutic use of chimeric antibodies, in vivo diagnostic use of an antitumor antibody labeled with a radioisotope and that the antibody can be conjugated to heterologous polypeptides or nucleic acids encoding such molecules such as cytokines. A routineer would have treated the autologous cell transplant recipient with the antilambda antibody to kill tumor cells present in the recipient. One of ordinary skill in the art at the time the invention was made would have been motivated to do the aforementioned because Uhr et al. teach antibody conjugate against lambda light chain wherein said antibody binds lambda light chain on tumor cells and wherein the conjugate is used to treat B cell tumors whilst Ruben et al. teach therapeutic use of chimeric antibodies, in vivo diagnostic use of an antitumor antibody labeled with a radioisotope and that the antibody can be conjugated to heterologous polypeptides or nucleic acids encoding such molecules such as cytokines and a routineer would have treated the autologous cell transplant recipient with the antilambda antibody to kill tumor cells present in the recipient.

Applicants arguments are as per addressed above.

6. No claim is allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ron Schwadron/
Ron Schwadron, Ph.D.
Primary Examiner, Art Unit 1644